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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,049	03/28/2002	Jorg Rosenberg	0480/01221	5165
26474	7590	10/01/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1615	
DATE MAILED: 10/01/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,049

Applicant(s)

ROSENBERG ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9-13 is/are rejected.
- 7) ☒ Claim(s) 4-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and affidavit filed 06/02/04.

The affidavit is in regards to translation of the German application 199 30 454.8 filed

07/02/1999. Claims 1-13 are pending.

Priority

Upon consideration, applicants' statement regarding the priority document is persuasive and receipt is acknowledged of the English translation of the German priority document.

Claim Rejections - 35 USC § 102

1. The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Krape et al.

(WO 99/00131, provided by applicants on Form PTO-1449) because applicants provide a verified translation of the foreign priority document, DE 199 30 454.8 filed 07/02/2000.

However, WO 99/00131 was published 07 January 1999 and remains prior art under 35 USC 102

(a). Thus claims 1-3 and new claims 9, 10 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Krape et al. (WO 99/00131). Same rejection applies here as was described for 35 USC 102(b).

Applicants argue that the method employed by Krape does not yield a product that is free of volatile organic solvents and that the preparations according to examples 5 and 6 contain 4% by weight of methanol and 14% by weight of ethanol respectively. Applicants also note that example 6 of Krape uses polyvinylpyrrolidone and not PEG 8000 as indicated in the heading of example 6 of Krape; that PEG-8000 will lead to preparations that is free residual organic solvent and PEG 8000 does not have glass transition temperature of $> 90^{\circ}\text{C}$.

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2. Applicants' arguments filed 06/02/04 have been fully considered but they are not persuasive.

The generic claim broadly claims polymer and as applicants admit in the remarks, the glass transition temperature of polyvinylpyrrolidone is higher than 90 °C. The polymer used in Krape in example 5 meets the limitation of the polymer. Examples 5 and 6 refer to examples 2 and 4 respectively and example 4 refers to example 2. The process of example 2 requires a drying step under vacuum pressure to remove residual solvents. Thus, contrary to applicants' assertion, there appears not to be residual solvent in example 2. Regarding a supposed "erroneous heading containing "PEG-8000," it cannot be categorically ascertained without checking with the inventors of the WO 99/00131. However, example 5 uses PVP, which applicants admit have glass transition temperature of >90 °C.

New claims 7-13 give rise to the rejection following.

3. Claims 1 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Miranda et al. (US 5,656,286).

Miranda discloses a transdermal drug delivery system that comprises a blend of at least two polymers and a soluble PVP, and a drug (abstract; column 2, lines 51-57; column 6, lines 26-34). "Typical PVP polymers are homopolymers of PVPs and the copolymer vinyl acetate vinylpyrrolidone (column 2, line 64 to column 3, line 1) and the homopolymeric PVP' are designated in the pharmaceutical industry as Povidone, Polyvidone, Copolyvidon and Copolyvidone (column 3, lines 2-7) to name a few. Paroxetine is one of the drugs that can be administered by the transdermal drug delivery system (column 18, line 16). Volatile organic solvent is used during the preparation of the device and the solvent is subsequently removed by

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evaporation (column 35, lines 24-26). Vinylpyrrolidone/vinyl acetate copolymer is copovidone (see Buhler et al., US 6,592,900, column 1, lines 13 and 14 as a teaching reference). The transdermal meets the limitation of solid or semisolid preparation. Miranda meets the limitation of the claims.

Claim Rejections - 35 USC § 103

4. The rejection of claims 4-6 under 35 U.S.C. 103(a) as being unpatentable over Krape et al. (WO 99/00131) in view of Craig et al. (WO 0032593) and further in view of Patel et al. (US 6,248,363) is withdrawn because Craig and Patel are not prior art over the instant claims since English translation of the DE 199 30 454.8 is provided. Applicants' argument is persuasive.

5. Claims 4-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not teach mixing the homogeneous melt in an extruder.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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